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OF MEDICAL INSTRUMENTATION

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Don't Miss...
**AAMI 31st Annual
Meeting & Exposition**
Philadelphia, PA
June 1-5, 1996

April 16, 1996

Office of the Secretary
Federal Communications Commission
Washington, DC 20554

Re: ET DOCKET No. 95-177
Amendment of Part 15 of the
Commission's Rules to Permit Operation
of Biomedical Telemetry Devices on
VHF-TV Channels 7-13 and on UHF TV Channels

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Dear Mr. Secretary:

The Association for the Advancement of Medical Instrumentation (AAMI) appreciates the opportunity to comment on the Notice of Proposed Rule Making (NPRM) to establish clear radio channels for ECG telemetry monitoring.

AAMI is a nonprofit membership organization whose mission is to provide multi-disciplinary leadership and programs that will enhance the ability of the professions, health care institutions, and manufacturing and other industries to develop and use safe and effective medical instrumentation and related technologies.

The membership consists of some 7,000 health care professionals, including experts in medical technology who are employed by government agencies (including the FDA); 1,500 hospitals; over 150 research and academic institutions; nearly 500 medical device manufacturers; and some 500 foreign members from all segments of the medical device community.

AAMI's membership accomplishes its objectives through national and international standards, publications, education, communications, networking, certification of technical personnel, and other programs.

Three of AAMI's corporate members--Hewlett Packard GMGH, Marquette Electronics, Inc., and SpaceLabs Medical, Inc.--also are members of the Critical Care Telemetry Group (CCTG), which petitioned the FCC to issue the NPRM. AAMI strongly supports the position of the CCTG and is joined, in doing so, by others of its members

The primary reason for endorsement of the NPRM by AAMI and its members is to provide interference-free monitoring of ECG for ambulatory patients during hospital stays and, more broadly, an interference-free environment for medical devices in general.

As one of AAMI's corporate members stated, the limited number of useable, interference-free telemetry channels available today to any one hospital unnecessarily restricts the use of telemetry for all patients who might benefit. In the current environment, telemetry devices enable continual monitoring of mobile patients within a limited area, thereby speeding recovery and reducing healthcare costs by decreasing the duration of hospitalization.

Future expectations are that medical telemetry will be used to monitor additional patient parameters, including more acutely ill patients. This expansion will create a need for more interference-free radio channels. In addition, interference with medical telemetry signals will become an even greater patient-safety issue.

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Another AAMI corporate member provided comments, detailed below, on some of the concerns raised by the FCC regarding implementation of the proposal. The numbers refer to specific paragraphs in the original FCC NPRM:

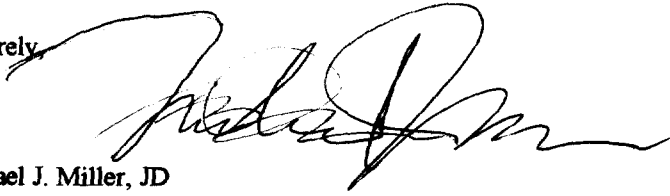
- Paragraph 7. Support allowing medical telemetry to continue using VHF channels 7 through 13 (174-216 MHz) but with higher power, as well as permitting medical telemetry access to the entire UHF band (470-806 MHz), excluding channel 37. This would enable flexibility to operate in the dynamic environment envisioned during deployment of DTV.
- Paragraph 8. Foresee no problem in designing a system that allows for flexibility in changing frequency.
- Paragraph 9. 5 milliwatts would enable medical telemetry to expand as technology evolves, without further requests for waivers, deviations or petitions from the FCC.
- Paragraph 10. Output power should be based on field strength, consistent with other FCC specifications, in addition to the fact that biomedical transmitters do not have an accessible port to measure power. The proposed out of band emission limit of 150 microvolts per meter is too restrictive, as the output power would be approximately 1000 times higher than this suggested limit. Therefore, a level of one-tenth the fundamental output would be recommended, in field strength terms, similar to other FCC part 15 unlicensed devices.
- Paragraph 11. Since current systems operate only on locally unused TV channels to prevent stations from interfering with telemetry, co-channel separation should not be an issue.
- Paragraph 12. The flexibility of a tunable system allows for spectrum sharing.
- Paragraph 13. Interference in residential neighborhoods should not be a problem, as telemetry would be operating on unused TV channels.
- Paragraph 14. The 200 kHz bandwidth requirement is sufficient.

Finally, in closing, AAMI would like to quote from yet another member, Doug McFarland, Biomedical Engineering Manager at Scott & White Memorial Hospital in Temple, TX, who expressed the viewpoint of an affected institution:

"Scott & White Memorial Hospital utilizes medical telemetry extensively for ambulatory patient monitoring. Telemetry not only makes ambulatory patient monitoring possible, it does so without the additional cost of structural modifications, cable and the labor cost associated with installation of hard wired monitoring systems. We feel that it is essential that needed regulatory adjustments be made to allow continued expansion of this technology to meet our patient needs, facilitate future innovation, and protect the quality of transmission."

In light of the current shortage of useable spectrum and the life-saving functions telemetry devices perform in healthcare institutions on a daily basis, AAMI urges the FCC to act favorably and quickly on the NPRM.

Sincerely,



Michael J. Miller, JD
President

cc: Government Relations Committee
Executive Committee